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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,610	11/29/2001	Brian A. Fox	00-96	7389

7590 03/26/2003

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EXAMINER
SNEDDEN, SHERIDAN

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,610	FOX ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *10 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7 is cancelled; Claims 1-6 and 8-25* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 16-21* is/are withdrawn from consideration.

5)☒ Claim(s) *11* is/are allowed.

6)☒ Claim(s) *6,8-10,12-15 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. This Office Action is in response to Paper #10, filed December 12, 2002. Claim 7 has been canceled. Applicant's amendment of claims 6, 8, 10, 11 and 12 is acknowledged. Applicant's addition of new claims 22-25 is acknowledged. Claims 1-5 and 16-21 have been withdrawn from consideration in Paper No: 8. Claims 6, 8-15 and 22-25 are under consideration.

Withdrawal of Objections and Rejections

2. The objections and/or rejections not explicitly restated or stated below are withdrawn.

Maintained Objections and Rejections

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6, 8-10, 12-15 and 22-25 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The above claims are directed to an isolated nucleic acid encoding a polypeptide of SEQ ID NO: 2, host cells, expression vectors and a method for producing the polypeptide of SEQ ID NO: 2, identified in the specification as Zarcp13. The specification asserts the nucleic acid has utility in the detection of Zarcp13 gene expression (page 62, line 20), in the production of Zarcp13 polypeptide and as having therapeutic use (page 85, line 21). Of the above uses, none provide a specific or substantial asserted utility or a well established utility. Basic research, such as studying the properties of the claimed product itself

or the mechanisms in which the material is involved, such as gene expression, do not constitute specific or substantial utilities. The therapeutic methods disclosed in the specification teach the treatment of unspecified disease or condition. Specifically, the specification merely states that the Zarcp13 nucleic acids may be provided to subjects in need of Zarcp13 treatment. Neither the specification nor the art of record disclose any diseases or conditions caused or exacerbated by Zarcp13. The asserted utility in this case essentially is a method of treating an unspecified, undisclosed disease or condition, which does not define a "real world" context of use. Treating an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use.

Additionally, the use of the nucleic acid in the method of making a polypeptide that itself has no specific and substantial asserted or well established utility is itself not specific and substantial or well establish. The specification as filed does not disclose or provide any evidence that points to an activity for the protein and furthermore there is no art of record that discloses or suggests any activity for the claimed protein. The specification discloses the Zarcp13 polypeptide as having potential use, or that may be evaluated for such potential use, as a modulator of energy balance and cellular metabolic reactions (page 74, line 15); as a antimicrobial (page 77, line 21); as a modulator of calcium ion concentration, muscle contraction, hormone secretion DNA synthesis or cell growth, etc (page77, line 35); as an inducer of platelet aggregation (page 76, line 21); as having therapeutic use thereof (page 83, line 3); and as having an educational use (page 84, line 20). Further experimentation is required to identify a specific and substantial use for the polypeptide as only prophetic uses not yet evaluated are disclosed in the specification. Furthermore, the non-prophetic uses disclosed for

the polypeptide, *e.g.* educational purposes, do not show specific utility as it states a general use of all polypeptides.

Thus, the claimed polynucleotide encoding protein is not supported by either a specific and substantial asserted utility or a well established utility as to the above because the specification fails to assert any well established utility for the protein and neither the specification as filed nor any art of record disclose or suggest any activity for the protein such that any utility would be well established for the protein.

4. Applicant's arguments filed December 12, 2002 in Paper No. 10, have been fully considered but they are not persuasive. Applicant argues on page 8 of the response that the above rejection is contrary to the law and examination guidelines. Additionally, on page 9 of the response, Applicant argues that the claimed invention, a nucleic acid molecule of the zacrp13 gene, has utility as a probe to detect and diagnose the presence of chromosome 22 monosomy and loss associated with meningiomas. Applicant's arguments have been fully considered. The rejection of claim 11 under 35 U.S.C. 101 has been withdrawn. The rejection under 35 U.S.C. 101 of claims 6, 8-10, 12-15 and 22-25 is maintained.

In order to function as a diagnostic probe for chromosome 22 monosomy and loss associated with meningiomas, the nucleic acid molecules of the present invention would have to maintain a high degree of specificity and homology to the native genomic sequence on chromosome 22 in order to hybridize under the stringent conditions required to produce convincing results necessary for proper diagnosis. Claims 6, 8-10, and 12-14 are directed to a genus of polynucleotides, both cDNA and genomic DNA, that would encode a polypeptide

defined by SEQ ID NO: 2 and fragments thereof. Due to the degeneracy of the genetic code, this genus would include millions of nucleic acid molecules or various sizes. Not all of these nucleic acid molecules would retain the utility of a probe for the diagnosis or meningiomas. The reduced homology of the degenerate nucleic acid molecules and the unpredictability of the would render them useless as an effective probe, thus the entire genus of polynucleotides is not enabled for the utility set forth by Applicant in Paper No. 10.

Furthermore, a subset of the above genus would span across more than one exon of the gene encoding the protein. This would be especially true for cDNA of the protein encoding SEQ ID NO: 2. In this case, the sequence of the cDNA molecules would be split across exons, reducing the portion of the molecule that would be effective for as a probe. This reduced portion size combined with the aforementioned reduced homology further limits the effectiveness of the entire genus of nucleic acid molecules. Taken together, not all of the nucleic acid molecules recited in claims 6, 8-10, and 12-14 have utility as a probe for the diagnosis of meningiomas.

Claim 15 is directed to a method of making a polypeptide and claims 22-25 further limit a polypeptide encoded by the nucleic acid. As stated in the rejection above, the polypeptide encoded by SEQ ID NO: 2 does not have a specific, substantial and well-establish utility. Thus, any claim to a protein or a method of making a protein that lacks utility, would itself lack utility.

The nucleic acid molecules and protein encoding recited in claims 6, 8-10, and 12-15 and 22-25 have been shown to lack a specific, substantial and well-establish utility in line with the law and examination guidelines.

Advisory Information

5. Claim 11 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3975 for regular communications and (703) 746-3975 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
March 23, 2003
SKS

Christopher S. F. Low
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SUPERVISORY PATENT EXAMINER
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